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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/711,961	09/06/1996	ARTHUR A. BRANSTROM	003/030/SAP	9506
7590	10/04/2005		EXAMINER	
MCMR-JA (JOHN MORAN) US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND FORT DETRICK FREDERICK, MD 217025012			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 10/04/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	08/711,961	BRANSTROM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 July 2003 and 23 May 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 56-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 56-65 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 29 July 2003 has been entered. Claims 56-65 are pending and under consideration.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 56, 57, 59-62, 64 and 65 stand rejected and claims 58 and 63 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable

over claims 9-17 of U.S. Patent No. 5,824,538. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 45-55 were rejected under the under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 and 34-43 of U.S. Patent No. 5,824,538 in the Office Action mailed 19 July 1999, which rejection was affirmed by the Board of Patent Appeals and Interferences in the decision of 30 May 2003 and summarily affirmed against claims 56, 57, 59-62 and 64-65 in the decision of 22 December 2003.

In a request for reconsideration mailed on 22 January 2004, Applicant contends that the Double Patenting rejection is overcome by the filing of a Terminal Disclaimer on 17 October 2003. However, the terminal disclaimer filed on 17 October disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of the '538 patent has been reviewed and is NOT accepted. The Terminal Disclaimer is not signed by an attorney or agent of record and the assignee has not established its ownership interest in the patent, in order to support the terminal disclaimer. There is no submission in the record establishing the ownership interest by either (a) providing documentary evidence of a chain of title from the original inventor(s) to the assignee, or (b) specifying (by reel and frame number) where such documentary evidence is recorded in the Office (37 CFR 3.73(b)). Therefore, claims 56, 57, 59-62, 64 and 65 stand rejected as unpatentable over the claims of the '538 patent. The rejection against claims 56, 57, 59-62, 64 and 65 is now set forth in full and applied to claims 58 and 63 herein below.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not patentably distinct from the reference claim(s) because the examined claim is

either anticipated by, or would be obvious over, the reference claim(s). The MPEP states, at §804,

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized “that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim,” but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first “determine how much of the patent disclosure pertains to the invention claimed in the patent” because only “[t]his portion of the specification supports the patent claims and may be considered.” The court pointed out that “this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 103, since only the disclosure of the invention claimed in the patent may be examined.”

In the instant case, the instant independent claim 56 is generic to all that is claimed in claim 15 of the ‘538 patent and therefore is anticipated by the patented claim. Independent claim 61 is generic to claim 15 of the ‘538 patent except that the *Shigella* of the instant claim is limited to being unable to synthesize active aspartate β-semialdehyde dehydrogenase. However, patented claim 11, which also depends from patented claim 9, is directed to a deposited strain that comprises this mutation and claim 17 recites that the *Shigella* strain of claim 9 comprises a mutation in the wild-type *asd* gene. Thus, a *Shigella* unable to synthesize active aspartate β-semialdehyde dehydrogenase is clearly within the scope of, and an obvious variant of the instant claim 15 as evidenced by the patented claims 11 and 17 and the portions of the specification that provide support for those claims. Likewise, claims 57-60 and 62-65 are not patentably distinct from the claims of the ‘538 patent because each of the limitations found in the claims are recited

in the claims that depend from patented claim 9 and, therefore, are obvious over the claims and the portions of the specification that define the claim limitations. For these reasons, the instant claims 56-65 are unpatentable over claims 9-17 of U.S. Patent No. 5,824,538.

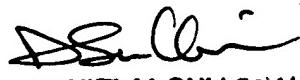
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.  
Examiner  
Art Unit 1636



DANIEL M. SULLIVAN  
PATENT EXAMINER